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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,953	06/21/2001	Dominique Bernard	016800-448	3212

7590

09/15/2003

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EXAMINER

WEBER, JON P

ART UNIT	PAPER NUMBER
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1651

13

DATE MAILED: 09/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/884,953

Applicant(s)

BERNARD ET AL.

Examiner

Jon P Weber, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10,11,13-24 and 27-35 is/are pending in the application.
- 4a) Of the above claim(s) 20-24 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10,11,13-19 and 28-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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Status of the Claims

The response with amendments filed 26 June 2003 has been received and entered. Claims 10-11, 13-24 and 27-35 have been presented for examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

This application contains claims 20-24 and 27 drawn to an invention nonelected **with** traverse in Paper No. 8, filed 04 November 2002. A complete reply to the final rejection **must** include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

N.B. As remarked at page 4 of the Office action of 27 December 2002, clarifying that claim 27 is drawn to an antibody would entail withdrawing it from further consideration.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 10-11 are now rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,274,364. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claim 1 of parent application is drawn to an isolated, substantially pure cathepsin L type cysteine protease that is present in healthy stratum corneum with a mass of 25-30 kDa. The instant claims are drawn to a fragment having a mass of 15-32 kDa and also being cathepsin L type cysteine protease. Never mind the impossibility of a fragment being larger than the parent, it is not clear how the instant claims are drawn to anything different from the patent claims, especially in view of the argument in the response that it is obvious to make fragments of the protease and screen for activity.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-11, 13-19 and 28-35 are now rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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The claims now recite "An isolated, substantially pure polypeptide fragment of a cathepsin L type cysteine protease ... has a cathepsin L type cysteine protease activity". The disclosure does not provide evidence that any such purified fragments were in possession. The pages alleging support for this change only describe determining that peak G4 has cathepsin L type cysteine protease activity. They do not support isolated, pure fragments having this range of molecular weight with this activity. Page 29 is the only place in the disclosure where a specific molecular weight corresponding to this activity is presented. Here the mass is 28 kDa. This is a new matter rejection.

Claims 10-11, 13-19 and 28-35 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for G4 peak cysteine protease, does not reasonably provide enablement for fragments thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with these claims.

It is argued that it is known in the art to use proteolysis to fragment proteins and that the resulting fragments can be assayed for the desired activity. Further, it is asserted that the fragments in the relied upon art demonstrates enablement even though the instant claims are drawn to a different protease (new limitations clarify this).

The mere fact that one can cleave proteins by proteolysis and assay the resulting fragments for a desired activity does not constitute enablement based upon state of the art. Usually proteolysis results in loss of biological activity, and is difficult to control or predict in the absence and even with available sequence data. In the instant case, no sequence data is

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available, little is known about the protein save a vague mass and an activity. One cannot predict how any given protease will fragment it. Given the highly unpredictable nature of working with two unknowns, it would require an undue burden of experimentation to make fragments, isolate them, and then assay for the desired activity without guidance or any reasonable expectation of success. As stated in *Brenner v Manson*, "A patent is not a hunting license." Make and test is not the standard for enablement.

Applicant's arguments filed 26 June 2003 have been fully considered but they are not persuasive. The rejection under 35 U.S.C. 112, first paragraph is adhered to for the reasons of record and the additional reasons above.

Claims 16 and 18-19 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for protease activity enhancers of claim 17, does not reasonably provide enablement for any activity enhancer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with these claims.

It is argued that one can simply test to see if a compound is an activity enhancer.

As remarked above, make and test is not the standard for enablement. There are millions of possible compounds in the universe of organic compounds. Of these, the disclosure only provides very limited guidance on the selection of suitable compounds. These are specifically enumerated in claim 17.

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Applicant's arguments filed 26 June 2003 have been fully considered but they are not persuasive. The rejection under 35 U.S.C. 112, first paragraph is adhered to for the reasons of record and the additional reasons above.

Claims 10-11, 13-19 and 28-35 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10 and 13 still recite molecular weight range from 15 to 32 kilodaltons. It is argued that "apparent molecular weight" is a term used in the art. Further it is argued that this language was allowed in the parent application.

While the term "apparent molecular weight" is used in the art, it is used in reference to a particular method of determining the mass. There are many physical techniques that can be used to determine macromolecular weights: sedimentation velocity, viscosity, osmotic pressure, SDS PAGE, gel filtration and mass spectrometry to name a few. Each method has limitations to precision and accuracy, and is used in different circumstances. The instant claim does not make reference to any particular method and therefore is inherently vague and indefinite. One cannot simply ignore the method of determination in reporting the mass. Furthermore, as stated in the Office action of 27 December 2002, there is no known method that obtains such a wide range of mass. It is not a question of incredibility. Finally, in the parent application, claim 1 recites a much narrower mass range (with reasonable error of 2-3 kDa around 28 kDa, *vide supra*) and does not discuss polypeptide fragments.

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1. An isolated, substantially pure cathepsin L type cysteine protease which is present in healthy stratum corneum contained in the cornified layer of the skin and having an apparent molecular weight ranging from 25 to 30 kilodaltons.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

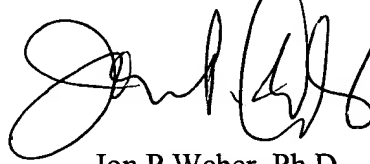
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P Weber, Ph.D. whose telephone number is 703-308-4015.

The examiner can normally be reached on daily, off 1st Fri, 9/5/4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in black ink, appearing to read 'Jon P. Weber', with a long horizontal line extending to the right.

Jon P Weber, Ph.D.
Primary Examiner
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JPW